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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,192	03/25/2004	Manne Satyanarayana Reddy	Bulk 3.0-045	6006
45776 7590 12/07/2007 DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862				
EXAMINER				
MOORE, SUSANNA				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
12/07/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/809,192

Applicant(s)

REDDY ET AL

Examiner

Susanna Moore

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 35-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,6-13,15-18 and 20-34 is/are allowed.
- 6) ☒ Claim(s) 2 and 14 is/are rejected.
- 7) ☒ Claim(s) 5 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, filed 10/2/2007, with respect to the Office Action mailed 4/2/2007 have been fully considered. This is a NonFinal Office Action. In summary, claims 1-34 are under consideration, while claims 35-38 are withdrawn.

This application contains claims 35-38, drawn to an invention nonelected with traverse in the paper of 1/8/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Specification

The disclosure is objected to because of the following informalities: the incorporation by reference to a foreign application or patent, or to a publication remains improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Appropriate correction is required. See page 1 and 12 of the Specification.

Claim Objections

The objection of claim 28 for the number “26” in the claim is withdrawn based on the amendment.

Claims 14 and 19 are objected to because of the following informalities: claims 14 and 19 state, “ $14, 19 \pm 0.09$ ” but this should be replaced with “ 14.19 ± 0.09 .” Appropriate correction is required.

Claim 5 is objected to because of the following informalities: claim 5 states “about 2839 cm^{-1} ” however Figure 2, the infrared spectrum, has a peak about 2939 cm^{-1} . Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 9-17 under 35 U.S.C. 112, second paragraph, for the preamble of claim 9 is drawn to a pharmaceutical composition but the claim does not recite a carrier is withdrawn based on the amendment.

Claims 2 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 states, “20 angles” but X-ray diffraction patterns are not normally measured in “20 angles.” Is this what Applicant intends?

Claim 14 states, “29 angles” but X-ray diffraction patterns are not normally measured in “29 angles.” Is this what Applicant intends?

Claim Rejections - 35 USC § 102

The rejection of claims 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Baltes et. al. (U.S. 4,525,358) is withdrawn based on the amendment.

The rejection of claims 1-17 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Duchene et al. (US 6,255,487) is withdrawn based on the declaration provided by Dr. Harikeerthi.

The rejection of claims 1-21 and 26-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Singh et. al. (WO 2004/103982 A1) is withdrawn based on the certified copy of the priority documents received.

Claim Rejections - 35 USC § 103

The rejection of claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et. al. (WO 2004/103982 A1) as applied to claims 22 and 23 above, and further in view of Johnson et. al. (US 2002/0012700 A1) or Sunshine et. al. (US 4,829,064) or Rubin (US 2002/0099058 A1) is withdrawn based on the certified copies of the priority documents.

Allowable Subject Matter

Claims 1, 3, 4, 6-13, 15-18 and 20-33 contain allowable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624